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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,738	05/31/2000	Hossein A. Ghanbari	018792/0180	2794

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/583,738	GHANBARI ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-33,35-47 and 49-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-30,33,35-44,47,49 and 50* is/are rejected.

7)☒ Claim(s) *31,32,45,46 and 51-58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22, 34 and 48 have been canceled.

Claims 23-33, 35-47 and 49-58 are pending.

Allowable Subject Matter

1. Claims 31-32, 45-46 and 51-58 contain allowable subject matter but depend from a rejected base claim, but would be allowable upon amendment into independent form.

Objections/Rejections Withdrawn

2. Claims 24,27,28,33(f) and 47(f) and 38 objected to because of the following informalities are no longer been obviated to in light of the amendment of the claims to provide antecedent basis, consistent tense or correct spelling of terms.

a. Claims 23, 35, 37 and 49 rejected under 35 U.S.C. 102(a) as being anticipated by Golosova et al, in light of the entire translated document is not available at this time, and the original document was published in Russian.

Rejections Maintained

b. Claims 23-25, 33, 37-39 and 47 rejected under 35 U.S.C. 102(b) as being anticipated by Norris (US Pat. 4,957,686) for reasons of record in paper numbers 18 and 20(paragraph 3).

3. Claims 23-24, 27, 29, 33, 37-38, 41, 43,47 rejected under 35 U.S.C. 102(b) as being anticipated by Unilever (EP 0414304 A2), for reasons of record in paper number 20, paragraph 10.

4. Claims 23-24,27,29,33,37-38,41,43,47 rejected under 35 U.S.C. 102(b) as being anticipated by Day et al (EP 0403292, 1990), for reasons of record in paper number 20, paragraph 11.

5. Claims 23-30, 33, 35-44, 47, 49-50 rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al (GB 2253859) in view of Merrill (US Pat 5,688,501), for reasons of record in paper number 20, paragraph 13.

Response to Arguments

6. Applicant's arguments filed March 10, 2004 have been fully considered but they are not persuasive.

7. The rejection of claims 23-25, 33, 37-39 and 47 under 35 U.S.C. 102(b) as being anticipated by Norris (US Pat. 4,957,686) is traversed on the grounds that :

c. Norris does not teach or suggest a bacteriophage capable of infecting more than one strain of S.sanguis

d. Norris does not indicate that the bacteriophage of Norris has a wide host range;

e. Norris does not teach serial isolation of phage preparations, by which the virulence of a phage can be dramatically increased.

8. It is the position of the examiner that :

9. Norris does teach or suggest bacteriophages that are capable of infecting more than one strain of bacteria. The guidance and teaching is through incorporation by reference to US Pat. 4,891,210 (see '686, col. 1, lines 44-52; col. 2, lines 1-11; col. 3, lines 42-45), as well as utilization of bacteriophage strains known in the art and deposited with the American Type Culture Collection (ATCC)(see '686, column 1, lines 56-57). Upon consideration of '210, at col. 2, bacteriophages are taught to provided "extended protection against acid production by L.acidophilis or similar strains", thus teaching the bacteriophage to infect not only L.acidophilis but other strains as well. Additionally the examiner consulted the ATCC website for bacteriophages for Streptococcus, at the time Norris was filed, and found a deposited strain of bacteriophage which are specific for a group of Streptococcus, which would infect a plurality of strains and species of bacteria.

10. With respect to wide host range, Norris claims a method of administering a preparation of bacteriophage that are specific for bacteria that produce a substance for "adhering to the salivary pellicle" which covers a broad host range of bacteria that would include S.mutans, S.sanguis, Lactobacilli, Actinomyes and various anaerobic bacteria (see '686, col. 3, lines 1-3 and col. 4, claim 1). With respect to a single bacteriophage being able to infect a plurality of strains or species of bacteria, ATCC teaches known bacteriophage species that will infect Streptococcus group C bacteria, this group includes a plurality of strains and species of Streptococcus (ATCC number 21597-B1), in addition to other bacterial species (ATCC deposits of bacteriophage are attached herewith).

11. With respect Norris teaching a method of serial isolation of phage preparations, by which the virulence of a phage can be dramatically increased, it is the position of the examiner that the claimed invention is not directed to a method of increasing the virulence of bacteriophages, but to treating infection with a preparation of bacteriophage, the claimed

methods not reciting preparations produced by a process that encompasses serial isolation. Applicant's arguments are not commensurate in scope with the instantly claimed methods steps. Norris '686, does disclose the propagation of phages in immense numbers, a process that is both practical and inexpensive (see '686, col. 1, lines 59-60). US Pat. 4,891,210 is incorporated by reference and discloses a method which includes propagating bacteriophages in cultures of host organism in liquid cultures (see '210, lines 3-7).

Applicant has not structurally distinguished the administered compositions from the administered compositions of Norris '686; Norris '686 inherently anticipates the instantly claimed invention.

12. The rejection of claims 23-24, 27, 29, 33, 37-38, 41, 43,47 under 35 U.S.C. 102(b) as being anticipated by Unilever (EP 0414304 A2), is traversed on the grounds that:

f. Unilever does not "teach Applicant's claimed purified, virulent, non-toxic, host specific bacteriophage preparations having a wide host range.";

g. Unilever is asserted to not teach serial isolation of phage preparations.

13. With respect to Applicant's assertion that the bacteriophage preparations of Unilever are not :

h. purified, the examiner would like to point to column 5, section "2.", which teaches the growth and purification of bacteriophages and column 4, lines 14-25, in which the bacteriophages are incorporated into toothpaste and mouth wash, and therefore must be isolated and purified compositions.

i. Virulent, see Unilever col. 2, lines 41-55, where the bacteriophages are disclosed to be capable of lysing one or more undesirable bacteria, and are therefore virulent to bacteria.

j. Non-toxic, see Unilever, col. 7, claim 3 "hygiene purposes", would include compositions that are non-toxic to skin (see claim 8, col. 7) and to the gums of the mouth (see claim 11) and for therapy (see claim 13).

k. Host specific, broad host range bacteriophages (see col. 2, lines 52-54 "infecting and lysing various types of bacteria", defines a broad host range bacteriophage, that is specific to bacterial host cells (see col. 1, lines 1-6).

14. It is the position of the examiner that none of the claims require the administration of bacteriophage preparations that were obtained from a serial isolation process; Applicant's arguments are not commensurate in scope with the instantly claimed method of treating a mammal. Even so, Unilever teaches a method of growing bacteriophages that includes at least first and second inoculations (see col. 5, lines 30-41 "again to re-inoculate more seeded broths and the procedure was repeated until a titer of more than 10^{10}/ml was obtained.") The reference inherently anticipates the instantly claimed invention.

15. The rejection of claims 23-24,27,29,33,37-38,41,43,47 under 35 U.S.C. 102(b) as being anticipated by Day et al (EP 0403292, 1990), is traversed on the grounds that:

l. Day et al does not "teach Applicant's claimed purified, virulent, non-toxic, host specific bacteriophage preparations having a wide host range.";

m. Day et al is asserted to not teach serial isolation of phage preparations; and

n. Day et al's examples are asserted to only show the isolation of bacteriophages that infect only a single bacteria.

16. With respect to Applicant's assertion that the bacteriophage preparations of Day et al are not :

o. purified, the examiner would like to point to page 5, lines 47-56, where the bacteriophage preparation is purified.

p. Virulent, see page 3, lines 50-52, "the use of lytic phages is generally preferred, as infection results in the rapid destruction of the target bacterium."

q. Non-toxic, see page 3, lines 35-36 "no adverse effect on flavour" and page 3, line 38 "so the food-stuff remains completely unaffected by their presence", and functions as a "medicament (see page 3, line 8)". "No danger to humans or animal being infected by the phage" (see page 3, lines 47-48).

r. Host specific, broad host range bacteriophages (see page 3, lines 45-49), "highly specific in the organisms they can infection, any one variety of phage will only infect one species of bacterium and frequently only selected strains of that species", thus teaching the bacteriophages to be specific for a plurality of strains, and specific for a species.

Additionally the reference discloses bacteriophage preparations directed against "several different species of bacterium" defining a broad host range preparation (see page 4, lines 6-8), and "specific for more than one family of bacterium" (see page 4, lines 18-19.)

17. It is the position of the examiner that none of the claims require the administration of bacteriophage preparations that were obtained from a serial isolation process; Applicant's arguments are not commensurate in scope with the instantly claimed method of treating a mammal. The reference inherently anticipates the instantly claimed invention.

18. The rejection of claims 23-30, 33, 35-44, 47, 49-50 under 35 U.S.C. 103(a) as being unpatentable over Day et al (GB 2253859) in view of Merrill (US Pat 5,688,501), is traversed on the grounds that:

s. Day et al does not "teach Applicant's claimed purified, virulent, non-toxic, host specific bacteriophage preparations having a wide host range.";

t. Day et al is asserted to not teach serial isolation of phage preparations; and

u. Day et al's examples are asserted to only show the isolation of bacteriophages that infect only a single bacteria.

19. It is the position of the examiner that Day et al teach the bacteriophage preparations to be:

v. purified, the examiner would like to point to page 7, paragraph 3, where the bacteriophage preparation is purified "ultracentrifugation and ultrafiltration".

w. Virulent, see page 5, paragraph 4, "the use of lytic phages is generally preferred, as infection results in the rapid destruction."

x. Non-toxic, see page 5, paragraph 2"tasteless and harmless" , "no danger to the consumer of being infected by the phage" (see page 4, paragraph 7).

y. Host specific, broad host range bacteriophages (see page 4, paragraph 6), highly specific in the organisms they can infect, any one variety of phage will only infect one species of bacterium and frequently only selected strains of that species", thus teaching the bacteriophages to be specific for a plurality of strains, and specific for a species.

Additionally the reference discloses bacteriophage preparations directed against "several different species of bacterium" defining a broad host range preparation (see page

6, paragraph 4), and "specific for more than one family of bacterium" (see page 8, paragraph 2).

20. It is the position of the examiner that none of the claims require the administration of bacteriophage preparations that were obtained from a serial isolation process; Applicant's arguments are not commensurate in scope with the instantly claimed method of treating a mammal. The reference inherently anticipates the instantly claimed invention.

21. Applicant further traverses the application of the combination of Day in view of Merril et al because Day does not teach a combination composition that contains antibiotics and additional bacteriophages for species of bacterial pathogens recited in the claims.

22. It is the position of the examiner that Day et al was not applied against the claims under 35 USC 102, but 35 USC 103. Both Day et al and Merril et al are directed to the formulation of bacteriophage preparations and the administration of the preparations to a mammal or animal(Day et al, see page 9, paragraphs 1-2; Merril et al (all claims and entire document) and therefore are analogous art.

Day et al teaches that addition of other components to the bacteriophage preparation, to include carrier material, encapsulation material, and an additive product (see page 7, last paragraph, and page 8, first and second paragraphs). Therefore, Day et al teaches a combination of components added to the bacteriophage preparations to aid in the effectiveness of the bacteriophage preparation. Merril et al teach bacteriophage preparations that contain a combination of components, one of which is an antibiotic, the antibiotic aiding in the bacteriophage preparation effectiveness against the target bacteria.

23. Merril et al is traversed to not disclose virulent bacteriophages having a broad host range.

24. It is the position of the examiner that Merril et al was cited to show genus specific bacteriophages (see Merril et al, claim 13) which would be specific for a plurality of species and strains of bacteria, thus defining bacteriophage preparations with a broad host range, and Merril et al additionally teach the incorporation of antibiotics into a bacteriophage preparation to aid in the overall effectiveness of the bacteriophage preparation.

25. Merril et al is traversed as not suggesting or teaching the combination of two or more bacteriophage strains.

26. It is the position of the examiner that Merril et al was not applied against the claims under 35 USC 102, but under 35 USC 103, and Day et al was cited for teaching the combination of two or more bacteriophages against two or more bacteria (see discussion of Day). Merril et al was applied against the claims in combination with Day et al, because Merril et al teach clinically relevant bacteria for which bacteriophage preparations are available and are effective at the genus level for killing bacteria (Bacteriophages are available from Internationally recognized Bacteriophage Depositories (ATCC or WHO)) and Merril et al also teach the combination of a bacteriophage preparation together with an antibiotic (see paper number 20, paragraph 2, incorporated herein by reference).

27. Applicant raises a question with respect to the full teaching set forth in Merril et al with respect to what the scope of the phrase "adjunctive or stand alone (see col. 7, line 30)" therapy is; the examiner therefore, for clarity of the record , relied upon Day et al who specifically teach combination compositions of bacteriophages directed against different genera/species/strains of bacteria in combination with Merril et al who Applicant agrees teaches the combination of bacteriophages with antibiotics, antimicrobial agents and chemotherapeutic agents. Day et al who teaches bacteriophage combination compositions directed against "several different species of bacterium (see Day et al, page 6, paragraph 6), such as bacteriophages specific for Clostridium together with Listeria was applied against the claims in view of Merril et al because Merril et al teach, suggest and provide guidance for the incorporation of antibiotics into bacteriophage preparations, and clearly points out clinically relevant bacteria for which bacteriophage therapy is needed. The claimed invention is obviated based on the combination of the teachings of Day et al in view of Merril et al, for reasons of record in paper number 20, paragraph 13, and response to arguments set forth herein.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

3. Agrawal et al (US Pat. 6,482,632) is cited to show a broad host range bacteriophage.
4. Averback et al (US Pat. 6,461,608) is cited to show bacteriophage useful in treating food products to prevent bacterial contamination.
5. Delisle (US Pat. 6,635,238) is cited to show bacteriophage enzymes for treatment and prevention of dental caries.
6. Fives-Taylor et al (US Pat. 4,659,561) is cited to show a method of treatment to prevent tooth decay.
7. Harris et al (US Pat. 6,656,463) is cited to show a method of reducing Salmonella through administering bacterial phage to pigs (swine).
8. Waddell et al (US Pat. 6,485,902) is cited to show a method of reducing levels of E.coli O157:h7 in a ruminant animal (see claims 4-7).

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp May 26, 2004

L. F. Smith

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